



Cortellis CMC Intelligence

新規申請対応

比較表を用いて調査対象の国々における要件概要の共通点と相違点を特定する

Summary comparison | 規制要件の概要比較

- “Summary”では、Home pageで選択した国・組織におけるCMC要件の概要を比較表形式で確認できます。
- この表示では、特定のトピックについて複数の国での規制要件を一覧することが可能です

選択した規制トピック

Home pageで選択した国について要件を比較可能

対象国、地域等の変更

Excelへの出力

Edit My Selection

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規制のトピック一覧から確認したい項目を選択

Home Pageで選択した国

My selection	Storage conditions	Submission type	Temperature (°C)	Relative Humidity (%)	Real time at submission (months)	Bracketing/Matrixing acceptance	Selection of batches	Stability commitment	Post-approval ongoing program	Testing frequency as per ICH	Extrapolation acceptance	Photostability
China	Refrigerator	NCE	5±3		12	Not specified	3 Pilot size batches using different API batches	3 Commercial batches until shelf life or retest period and one batch per year	Yes	Yes	Yes	Yes
China	General case	Generic	25±2	60±5	6	Not specified	3 Pilot size batches using different API batches	3 Commercial batches until shelf life or retest period and one batch per year	Yes	Yes	Yes	Yes
China	General case	Generic	30±2	65±5	6	Not specified	3 Pilot size batches using different API batches	3 Commercial batches until shelf life or retest period and one batch per year	Yes	Yes	Yes	Yes
China	Refrigerator	Generic	5±3		6	Not specified	3 Pilot size batches using different API batches	3 Commercial batches until shelf life or retest period and one batch per year	Yes	Yes	Yes	Yes
China	Freezer	Generic	-20±5		6	Not specified	3 Pilot size batches using different API batches	3 Commercial batches until shelf life or retest period and one batch per year	Yes	Yes	Yes	Yes
China	General case	NCE	25±2	60±5	12	Not specified	3 Pilot size batches using different API batches	3 Commercial batches until shelf life or retest period and one batch per year	Yes	Yes	Yes	Yes
China	Freezer	NCE	-20±5		12	Not specified	3 Pilot size batches using different API batches	3 Commercial batches until shelf life or retest period and one batch per year	Yes	Yes	Yes	Yes
China	General case	NCE	30±2	65±5	12	Not specified	3 Pilot size batches using different API batches	3 Commercial batches until shelf life or retest period and one batch per year	Yes	Yes	Yes	Yes
India	General case	N/A	30±2	75±5	12	No	3 Pilot size batches	3 Commercial batches until shelf life or retest period and one batch per year	Yes	Yes	Yes	Yes

例：アジア各国の低分子医薬品新規申請時の不純物に関する要件比較を行う

The screenshot displays the Clarivate regulatory database interface. At the top, the 'Small Molecules' tab is selected, highlighted with a yellow box and a blue callout box containing the text 'Small Moleculesを選択'. Below this, the 'Pre-Approval' radio button is selected and highlighted with a yellow box. The main navigation area includes tabs for 'Countries / Territories (8)', 'Regions', 'Organizations', 'Member States', and 'Climatic Zones'. The 'Countries / Territories (8)' tab is highlighted with a yellow box, and a blue callout box with the text '対象国を選択する' points to the dropdown menu below it. The dropdown menu shows 'Select Countries / Territories' with a downward arrow. Below the dropdown, a section titled 'Countries / Territories Selected (8)' displays a list of selected countries: China, Indonesia, Japan, Philippines, South Korea, Taiwan, Thailand, and Vietnam, each with a close button (X). A 'Clear all' link is visible to the right. At the bottom, the 'Go to:' section contains four buttons: 'Summary', 'Detailed', 'Report', and 'Updates'. The 'Summary' button is highlighted with a yellow box, and a blue callout box with the text 'Summaryをクリック' points to it. The Clarivate logo is located in the bottom left corner.

例：アジア各国の低分子医薬品新規申請時の不純物に関する要件比較を行う

[Home](#)
[Summary](#)
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Summary Requirements

CMC Requirements

Nomenclature

Compendial standards

Details of manufacturer

Quality documentation

Impurities

Physicochemical and biological properties

Accelerated Stability - Drug Substance

Long-term Stability - Drug Substance

Accelerated Stability - Drug Product

Long-term Stability - Drug Product

Marketing Authorization Application Requirements

Medicines Procurement

Impurities

[Table Glossary](#)

New [Edit My Selection](#)

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My selection	Reporting threshold	Identification threshold	Qualification threshold
China	According to current ICH guideline Q3A: Maximum Daily Dose: ≤ 2g/day - 0.05% Maximum Daily Dose: > 2g/day - 0.03%	According to current ICH guideline Q3A: Maximum Daily Dose: ≤ 2g/day - 0.10% or 1.0 mg per day intake (whichever is lower) Maximum Daily Dose: > 2g/day - 0.05%	According to current ICH guideline Q3A: Maximum Daily Dose: ≤ 2g/day - 0.15% or 1.0 mg per day intake (whichever is lower) Maximum Daily Dose: > 2g/day - 0.05%
Indonesia	According to ICH guideline Q3A (New Drug Substances) and Q3B (New Drug Product). <ul style="list-style-type: none"> Maximum Daily Dose: ≤ 2g/day - 0.05% Maximum Daily Dose: > 2g/day - 0.03% 	According to ICH guideline Q3A (New Drug Substances) and Q3B (New Drug Product). <ul style="list-style-type: none"> Maximum Daily Dose: ≤ 2g/day - 0.10% or 1.0 mg per day intake (whichever is lower) Maximum Daily Dose: > 2g/day - 0.05% 	According to ICH guideline Q3A (New Drug Substances) and Q3B (New Drug Product). <ul style="list-style-type: none"> Maximum Daily Dose: ≤ 2g/day - 0.15% or 1.0 mg per day intake (whichever is lower) Maximum Daily Dose: > 2g/day - 0.05%
Japan	According to ICH guideline Q3A: <ul style="list-style-type: none"> Maximum Daily Dose: ≤ 2g/day - 0.05% Maximum Daily Dose: > 2g/day - 0.03% 	According to ICH guideline Q3A: <ul style="list-style-type: none"> Maximum Daily Dose: ≤ 2g/day - 0.10% or 1.0 mg per day intake (whichever is lower) Maximum Daily Dose: > 2g/day - 0.05% 	According to ICH guideline Q3A: <ul style="list-style-type: none"> Maximum Daily Dose: ≤ 2g/day - 0.15% or 1.0 mg per day intake (whichever is lower) Maximum Daily Dose: > 2g/day - 0.05%
Philippines	Not specified	Not specified	Not specified
South Korea	According to ICH guideline Q3A (New Drug Substances) and Q3B (New Drug Product)	According to ICH guideline Q3A (New Drug Substances) and Q3B (New Drug Product)	According to ICH guideline Q3A (New Drug Substances) and Q3B (New Drug Product)
Taiwan	According to ICH guideline Q3A: Maximum Daily Dose: ≤ 2g/day - 0.05% Maximum Daily Dose: > 2g/day - 0.03%	According to ICH guideline Q3A: Maximum Daily Dose: ≤ 2g/day - 0.10% or 1.0 mg per day intake (whichever is lower) Maximum Daily Dose: > 2g/day - 0.05%	According to ICH guideline Q3A: Maximum Daily Dose: ≤ 2g/day - 0.15% or 1.0 mg per day intake (whichever is lower) Maximum Daily Dose: > 2g/day - 0.05%
Thailand	According to ICH guideline Q3A: Maximum Daily Dose: ≤ 2g/day - 0.05% Maximum Daily Dose: > 2g/day - 0.03%	According to ICH guideline Q3A: Maximum Daily Dose: ≤ 2g/day - 0.10% or 1.0 mg per day intake (whichever is lower) Maximum Daily Dose: > 2g/day - 0.05%	According to ICH guideline Q3A: Maximum Daily Dose: ≤ 2g/day - 0.15% or 1.0 mg per day intake (whichever is lower) Maximum Daily Dose: > 2g/day - 0.05%
Vietnam	According to ICH guideline Q3A (New Drug Substances) and Q3B (New Drug Product). <ul style="list-style-type: none"> Maximum Daily Dose: ≤ 2g/day - 0.05% Maximum Daily Dose: > 2g/day - 0.03% 	According to ICH guideline Q3A (New Drug Substances) and Q3B (New Drug Product). <ul style="list-style-type: none"> Maximum Daily Dose: ≤ 2g/day - 0.10% or 1.0 mg per day intake (whichever is lower) Maximum Daily Dose: > 2g/day - 0.05% 	According to ICH guideline Q3A (New Drug Substances) and Q3B (New Drug Product). <ul style="list-style-type: none"> Maximum Daily Dose: ≤ 2g/day - 0.15% or 1.0 mg per day intake (whichever is lower) Maximum Daily Dose: > 2g/day - 0.05%

Summary Requirements
 ↓
 CMC Requirements
 ↓
 Impuritiesを選択