

SOP Title	SOP No.	Version No.	Effective date
Surveillance of Adverse Reaction Reports	QA.SOP-013	00	YYYY/MM/DD

SURVEILLANCE OF ADVERSE REACTION REPORTS

Written by:	[Name]	Signature/Date	[YYYY/MM/DD]
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1. Purpose

1.1. This procedure describes the adverse reaction monitoring program and defines the process by which adverse reaction summary reports are created and submitted to authorities. It thus serves to increase cumulative knowledge about product safety based on actual use.

2. Scope

2.1. This procedure applies to adverse reaction summary reports which are prepared annually and submitted to Health Canada upon request.

3. Responsibilities

3.1. **Quality Assurance (QA)/Responsible Person (RP):** Responsible for collecting all adverse reaction data and documenting it in the appropriate summary report file.

3.2. **Responsible Person (RP):** Responsible for submitting all adverse reaction summary reports to Health Canada, as required.

4. Acronyms and Definitions

4.1. **Adverse Reaction:** A noxious and unintended response to a product where a causal relationship between the product and the occurrence of the adverse reaction is suspected.

4.2. **Baseline safety information:** Safety information based on the company's baseline data. This is a subset of product information for periodic adverse event reports.

4.3. **Canada Vigilance Program (CVP):** A Health Canada program responsible for collecting and evaluating marketed health product-related adverse reaction reports.

4.4. **Clinical trial:** Research involving human subjects, the purpose of which is to discover or verify the clinical or pharmacological effects of a drug for human use.

4.5. **International Marketing Date (DIMM) :** The date of first authorization to market the product. This date is usually the first date that the product was sold.

4.6. **Serious adverse effect:** A noticeable and unintended reaction to a cannabis product that requires hospitalization or prolongation of hospitalization, causes birth defects results in lasting or significant disability, is life-threatening or causes death.

SOP TO BE CONTINUED...